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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/318,870	05/26/1999	ANDREW H. SEGAL	3378/80489	2018

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EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/09/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/318,870

Applicant(s)

Segal, Andrew

Examiner

DeCloux, Amy

Art Unit

1644

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Jan 4, 2002

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-25 is/are pending in the application

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☒ Claims 1-25 are subject to restriction and/or election requirements

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other:

### Detailed Action

Note: The Group and Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Amy DeCloux, Group Art Unit 1644, Group 1640, Technology Center 1600.

In view of applicant's amendment of claim 1, filed 1-4-02 (Paper No. 19), a new restriction requirement is set forth below.

1. A restriction is required under 35 USC 121 between one of the following groups:

I. Claims 1-2, 5-8, 13-14, 17-20 and 22-25, drawn to a method of vaccinating a mammal to a selected antigen, the method comprising administering to a mammal a vaccine composition comprising a cytokine coated cell comprising said selected antigen, classified in class 424, subclass 93.2,

II. Claims 3-4, drawn to a method of vaccinating a mammal to a selected antigen, the method comprising administering to a mammal a vaccine composition comprising a cytokine coated cell comprising said selected antigen, further comprising an opsonin-enhanced cell, classified in class 424, subclass 93.2,

III. Claims 9-12, drawn to a method of vaccinating a mammal to a selected antigen, the method comprising; contacting an APC in vitro with a cytokine coated cell comprising a selected antigen and said cytokine, classified in class 424, subclass 93.2,

IV. Claims 10-12, drawn to a method of vaccinating a mammal to a selected antigen, the method comprising; contacting an APC in vitro with a cytokine coated, opsonin enhanced cell comprising a selected antigen and an opsonin, classified in class 424, subclass 93.2,

V. Claims 1-2, 5-8, 15-16, 17-20 and 22-25, drawn to a method of vaccinating a mammal to a selected antigen, the method comprising administering to a mammal a vaccine composition comprising a cytokine coated cell comprising said selected antigen, wherein the receptor encompassed by claim 15 is the IL-2 receptor and the ligand encompassed by claim 16 is IL-2, classified in class 424, subclass 93.2,

VI. Claims 1-2, 5-8, 15-16, 17-20 and 22-25, drawn to a method of vaccinating a mammal to a selected antigen, the method comprising administering to a mammal a vaccine composition comprising a cytokine coated cell comprising said selected antigen, wherein the receptor encompassed by claim 15 is the IL-4 receptor and the ligand encompassed by claim 16 is IL-4, classified in class 424, subclass 93.2,

VII. Claims 1-2, 5-8, 15-16, 17-20 and 22-25, drawn to a method of vaccinating a mammal to a selected antigen, the method comprising administering to a mammal a vaccine composition comprising a cytokine coated cell comprising said selected antigen, wherein the receptor encompassed by claim 15 is the IL-6 receptor and the ligand encompassed by claim 16 is IL-6, classified in class 424, subclass 93.2,

VIII. Claims 1-2, 5-8, 15-16, 17-20 and 22-25, drawn to a method of vaccinating a mammal to a selected antigen, the method comprising administering to a mammal a vaccine composition comprising a cytokine coated cell comprising said selected antigen, wherein the receptor encompassed by claim 15 is the IL-10 receptor and the ligand encompassed by claim 16 is IL-10, classified in class 424, subclass 93.2,

IX. Claims 1-2, 5-8, 15-16, 17-20 and 22-25, drawn to a method of vaccinating a mammal to a selected antigen, the method comprising administering to a mammal a vaccine composition comprising a cytokine coated cell comprising said selected antigen, wherein the receptor encompassed by claim 15 is the IL-12 receptor and the ligand encompassed by claim 16 is IL-12, classified in class 424, subclass 93.2,

X. Claims 1-2, 5-8, 15-16, 17-20 and 22-25, drawn to a method of vaccinating a mammal to a selected antigen, the method comprising administering to a mammal a vaccine composition comprising a cytokine coated cell comprising said selected antigen, wherein the receptor encompassed by claim 15 is the TNF- $\alpha$  receptor and the ligand encompassed by claim 16 is TNF- $\alpha$ , classified in class 424, subclass 93.2,

XI. Claims 1-2, 5-8, 15-16, 17-20 and 22-25, drawn to a method of vaccinating a mammal to a selected antigen, the method comprising administering to a mammal a vaccine composition comprising a cytokine coated cell comprising said selected antigen, wherein the receptor encompassed by claim 15 is the IFN- $\gamma$  receptor and the ligand encompassed by claim 16 is IFN- $\gamma$ , classified in class 424, subclass 93.2,

XII. Claims 1-2, 5-8, 15-16, 17-20 and 22-25, drawn to a method of vaccinating a mammal to a selected antigen, the method comprising administering to a mammal a vaccine composition comprising a cytokine coated cell comprising said selected antigen, wherein the receptor encompassed by claim 15 is a specific chemokine and the ligand encompassed by claim 16 is a specific chemokine receptor, classified in class 424, subclass 93.2,

XIII. Claims 21-25, drawn to a method of vaccinating a mammal to a selected antigen, the method comprising administering to a mammal a vaccine composition comprising an opsonin enhanced pathogenic cell and a cytokine coated pathogenic cell, classified in class 424, subclass 93.2.

Note: each claim will be examined only to the extent of the elected invention,

The inventions are distinct, each from the other because:

2. Groups I-XIII are unique methods, because though each method has the same endpoint, each method comprises administering a different combination of ingredients, which though said ingredients overlap, they are not coextensive. Therefore, Groups V-IX are patentably distinct.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search in the non-patent literature of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

4. Regardless which group is elected is elected, applicant is further required under 35 U.S.C. 121:

to elect a method comprising a specific mammal, a specific cytokine, a specific cell coated with cytokine, a specific cell that is opsonized, a specific opsonin, a specific ligand, a specific lipid and a specific receptor.

5. Claims 1-25 are generic in at least one aspect.

6. The species are distinct each from the other for the following reasons:

mammals comprise different animals each with a distinct structure and distinct physiochemical properties,

cytokines comprise different molecules each with a distinct structure and distinct physiochemical properties,

cells coated with cytokine comprise different composites, each with a distinct structure and distinct physiochemical properties ,

cells that are opsonized comprise different composites each with a distinct structure and distinct physiochemical properties,

opsonins comprise different molecules each with a distinct structure and distinct

physiochemical properties,

ligands comprise different molecules each with a distinct structure and distinct physiochemical properties,

lipids comprise different molecules each with a distinct structure and distinct physiochemical properties,

and receptors comprise different molecules each with a distinct structure and distinct physiochemical properties,

7. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax

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number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers (**other than elections**) should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.  
Patent Examiner  
Group 1640, Technology Center 1600  
April 8, 2002

*Amy DeCloux*  
4-8-02